UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	**MDL No. 2875**
THIS DOCUMENT RELATES TO ALL CASES	**HON. ROBERT B. KUGLER** **CIVIL NO. 19-2875 (RBK)** **Redacted Version**

PLAINTIFFS' *DAUBERT* MOTION AND INCORPORATED MEMORANDUM OF LAW TO PRECLUDE OPINIONS OF DEFENSE EXPERT ROGER WILLIAMS, M.D.

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I. INTRODUCTION

Plaintiffs submit this *Daubert* motion against Teva's expert, Roger Williams, M.D., with regard to his opinions [redacted] These opinions are unreliable, unreliably applied, and unhelpful because they do not rest on a reliable methodology or sufficient facts or data.

Like Teva's other expert, Mr. Timothy Anderson, Dr. Williams opines that a [redacted] From this faulty premise, Dr. Williams extrapolates that, [redacted]

Dr. Williams' [redacted] are fatally flawed. For one, the FDA *expressly stated* that ZHP's valsartan API *was adulterated*. Therefore, Teva's VCDs incorporating that same adulterated API were adulterated as well.

More fundamentally, an adulterated product is one not made in a cGMP-compliant manner, or that lacks appropriate purity, quality, identity, and other characteristics. Teva's VCDs fell into each of these buckets for years prior to the

July 2018 recalls. Dr. Williams lacks any basis for [redacted] Were his peculiar view correct, then a firm [redacted]. This is akin to saying a state-law tort claim cannot lie against a firm that negligently sold poisoned milk because the plaintiff already bought and drank the milk before the poison was discovered by the FDA (or anyone else). Dr. Williams' [redacted] flow from an unreliable methodology untethered to law or fact, rendering them unhelpful.

Dr. Williams also proffers speculative opinions about [redacted] Thus, his opinions simply lack sufficient facts or data. His after-the-fact speculation about what [redacted] are not the proper subject of expert opinion.

For these reasons, expressed more fully below, Dr. Williams' opinions identified herein should be precluded.

II. LEGAL STANDARD

A. Rule 26 and the Contents of the Expert Report

Federal Rule of Civil Procedure 26(a)(2) governs the disclosure of expert testimony and specifically the contents of an expert report. Relevant to this Motion, the Rule states the following: "The report must contain: (i) a complete statement of all opinions the witness will express and the basis and reasons for them; (ii) the facts or data considered by the witness in forming them …." Fed. R. Civ. P. 26(a)(2)(B)(i) & (ii). A failure to submit an expert report that complies with Rule 26 is an independent basis for the exclusion of the expert's testimony. *See, e.g., Meyers v. Nat'l R.R. Pass. Corp. (Amtrak)*, 619 F.3d 729, 734 (7th Cir. 2010) ("The consequence of non-compliance with Rule 26(a)(2)(B) is exclusion of an expert's testimony[.]" (internal quotations and citations omitted)).

Experts are therefore only permitted to testify at trial in accordance with the contents of their reports. *See* Fed. R. Civ. P. 26(a)(2)(B)(i); *see also Lipton v. Mountain Creek Resort, Inc.*, No. CV134866KMMAH, 2019 WL 4597205, at *7 (D.N.J. Sept. 23, 2019) ("[T]he court generally will not permit an expert to testify beyond the scope of his or her report."). "Compliance with Rule 26(a)(2) is thus a condition precedent to the use of expert testimony at trial." *ABB Air Preheater, Inc. v. Regenerative Env't Equip. Co.*, 167 F.R.D. 668, 671 (D.N.J. 1996).

B. *Daubert* Standard

The admissibility of expert testimony is determined pursuant to Federal Rule of Evidence 702. The party offering the proposed expert testimony bears the burden of establishing the admissibility of the testimony by a preponderance of the evidence. *Padillas v. Stork-Gamco, Inc.,* 186 F.3d 412, 417-18 (3d Cir. 1999). An "expert's opinions must be based on the methods and procedures of science, rather than on subjective belief or unsupported speculation." *In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717, 742 (3d Cir. 1994) (citations and internal quotations omitted). Thus, "the expert must have 'good grounds' for his or her belief." *Id.* (quoting *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 590 (1993)). These good grounds must support each step of the analysis and, "*any* step that renders the analysis unreliable under the *Daubert* factors renders the expert's testimony inadmissible." *Id.* at 745. Judges within this Circuit also consider how and when the methodology is used outside of litigation. *Paoli*, 35 F.3d at 742 (discussing reliability factors under *Daubert* and Third Circuit case law).

Furthermore, "*Daubert*'s gatekeeping requirement .... make[s] certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.'" *Elcock v. Kmart Corp.*, 233 F.3d 734, 746 (3d Cir. 2000) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152

(1999)); *see also Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 594 (D.N.J. 2002*), aff'd,* 68 Fed. App'x 356 (3d Cir. 2003). In addition, the following factors are relevant when determining reliability:

> (i) whether the expert's proposed testimony grows naturally and directly out of research the expert has conducted independent of the litigation (*see Daubert v. Merrell Dow Pharmaceuticals, Inc.,* 43 F.3d 1311, 1317 (9th Cir. 1995)); (ii) whether the expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion (*see General Elec. Co. v. Joiner,* 522 U.S. 136, 146, 118 S. Ct. 512, 139 L.Ed.2d 508 (1997)); (iii) whether the expert has adequately accounted for alternative explanations (*see Claar v. Burlington, N.R.R.,* 29 F.3d 499 (9th Cir. 1994)).

Magistrini, 180 F. Supp. 2d at 594–95.

III. ARGUMENT

A. Dr. Williams' [redacted] Should Be Precluded[1]

A product is adulterated

> if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

[1] Because Teva's experts, Dr. Williams and Mr. Anderson, share the same flawed [redacted], this section largely appears verbatim in this Motion as well as the contemporaneously filed motion to preclude Mr. Anderson's opinions.

21 U.S.C. § 351(a)(2)(B).[2] Contamination renders a drug adulterated, as does failure to comply with any cGMP regulation concerning the manufacture, processing, packing or holding of a drug (even in the absence of contamination). *See id.*; *see also* 21 C.F.R. § 210.1(b). Both past and future cGMP violations may result in adulteration. *See, e.g.*, *United States v. Barr Labs., Inc.*, 812 F. Supp. 458, 487 (D.N.J. 1993) (discussing both past and future cGMP violations resulting in adulteration).

Expert testimony that is contrary to law or fact, or that seeks to misstate the applicable law to the jury, is unhelpful. *See, e.g.*, *SEC v. Ambassador Advisors, LLC*, 576 F. Supp. 3d 250 (E.D. Pa. Dec. 21, 2021). An expert's opinion is inadmissible if it "is both contrary to the record . . . [and] is contrary to the law." *See, e.g.*, *Apotex, Inc. v. Cephalon, Inc.*, 321 F.R.D. 220, 236 (E.D. Pa. 2017). Dr. Williams' adulteration opinions should be precluded they unreliably run contrary to law and fact, as discussed more fully below.

1. [redacted] *See* Ex. 1 (Williams 1/28/23 Corrected Rpt.) at

[2] For ease, this Motion refers to federal law, but of course Plaintiffs' claims arise under parallel, non-preempted state laws that impose identical state requirements.

¶ 144; Ex. 2 (Williams 1/31/23 Tr.) at 233:12 – 234:25; Ex. 3 (Williams 2/17/22 Tr.) at 302:26-24.[3] [redacted]. *See* Ex. 1 at ¶¶ 22, 145. [redacted].

Dr. Williams' belief that, [redacted] simply is incorrect. [redacted]. *See, e.g.*, *United States v. 789 Cases, More or Less, of Latex Surgeons' Gloves, an Article of Device*, 799 F. Supp. 1275, 1296 (D.P.R. 1992).

Adulteration does not turn on whether the FDA, with its limited resources, catches a firm violating cGMP and issues a formal statement about it. Rather, each firm engaged in the manufacture and distribution of drugs has self-executing obligations to ensure its products and practices comply with cGMP at all times. As the FDA puts it: "If a company is not complying with CGMP regulations, any drug it makes is considered 'adulterated' under the law. This kind of adulteration means

[3] Dr. Williams submitted a declaration and gave testimony at the class certification stage that included the [redacted]. He confirmed his prior testimony during his liability-stage deposition last month. *See* Ex. 2 at 22:8 – 23:4.

that the drug was not manufactured under conditions that comply with CGMP."[4] Even Dr. Williams himself waffles on his bold new litigation-generated opinions about adulteration. Contrary to his latest opinions, he testified last year that a product can be adulterated even absent formal FDA action. *See* Ex. 3 at 138:24 – 139:6;[5] *id.* at 140:5-16.[6]

Despite being contrary to law, fact, and common sense, Dr. Williams' [redacted]

[redacted]

[4] Facts About the Current Good Manufacturing Practices (CGMPSs), *at* https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practices-cgmps (last visited Feb. 17, 2023); *see also* 21 C.F.R. §§ 210.1, 211.1.

[5] [redacted]

[6] [redacted]

Here, [redacted]. *See* Ex. 4. [redacted] *Id.*

That same ZHP valsartan API had been incorporated into each and every one of Teva's VCDs at issue at this stage of the case. Teva's own corporate designees confirmed, one after the other, [redacted]

[7] *See, e.g.*, Ex. 8 (Lyons Tr.) at 285:3-12 [redacted].

[redacted]. Ex. 3 (Williams 2/17/22 Tr.) at 40:7-15.[8] [redacted].[9]

As ZHP's valsartan API was contaminated and made in violation of cGMPs, so too, were Teva's VCDs incorporating same. It is baseless, illogical, counterfactual, and certainly unhelpful to the jury for [redacted]

[8] [redacted]

[9] Ex. 8 (Lyons Tr.) at 130:3 – 132:2 [redacted] *see also id.* at 275:24 – 276:5.

[redacted]

2. [redacted]

Dr. Williams also erroneously contends adulteration [redacted] *See* Ex. 1 at ¶¶ 142, 145.

As a threshold matter, the FDA's December 2018 interim limits are immaterial. As Dr. Williams concedes, [redacted].

[10] Ex 2 (Williams 1/31/23 Tr.) at 92:11-18.

[11] Ex. 3 (Williams 2/17/22 Tr.) at 102:7 – 103:24.

More to the key point, the record, caselaw, and even his own prior testimony belies Dr. Williams' dubious position that [redacted]. *See, e.g.*, *BCBS v. GlaxoSmithKline*, No. 13-4663, 2019 WL 4751883, at *1 (E.D. Pa. Sept. 30, 2019) (seeking economic damages years lates for drugs purchased between 2000 to 2005 that were later considered to be adulterated due to cGMP violations); *United States v. Titan Med. Enterprises, Inc.*, No. 2:11-cv-10752, 2013 WL 444034, at *1 (C.D. Cal. Feb. 4, 2013) (noting, in 2013, that "[f]rom 2001 through 2012, Defendants' drug manufacturing operations did not comply with current good manufacturing practice regulations for drugs . . . Defendants' drugs are therefore adulterated under 21 U.S.C. § 351(a)(2)(B)."); *Barr*, 812 F. Supp. at 487 ("no dispute" about firm's "past violations" of cGMP); *see also* Ex. 5 (DOJ press release of May 2013 discussing generic drug manufacturer's cGMP violations leading to adulterated product made years prior in 2005 and 2006).

ZHP's expert, Mr. David Chesney, also confirmed that [redacted]

[redacted] Ex. 6 (Chesney Tr.) at 189:24-190:3, 195:16-23. Dr. Williams himself also acknowledges that Teva's head of quality and Rule 30(b)(6) designee recognized that [redacted]. *See* Ex. 7 ([redacted]); *see also* Ex. 2 (Williams 1/31/23 Tr.) at 235:20 – 236:1.[12] [redacted]

Dr. Williams' strained position further lacks common sense. According to him, [redacted]

12 [redacted]

[redacted]. Unsurprisingly, Dr. Williams cites no legal, regulatory, or factual support for his astonishing position.

Absent any credible basis in law or fact, Dr. Williams' [redacted] are unreliable, the product of unreliable methods, and unhelpful.

B. Dr. Williams' Speculative Opinions About [redacted] Should Be Precluded

[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

Opinions not rooted in sufficient facts are unreliable. *See* Fed. R. Evid. 702(b); *United States ex rel. Penelow v. Janssen Prod., LP*, No. CV127758ZNQLHG, 2022 WL 94535, at *3 (D.N.J. Jan. 10, 2022) ("The purported expert's testimony "must be based on the 'methods and procedures of science' rather than on 'subjective belief or unsupported speculation.'"). Opinions that rest on "assumptions and conclusions that are not supported by the factual record" have been excluded on the basis that they would not "aid the jury in resolving a factual dispute" because they do not "fit under the facts of the case." *Meadows v. Anchor Longwall & Rebuild, Inc.*, 306 Fed.

App'x 781, 790 (3d Cir. 2009) (internal citations and quotations omitted).[13] Further, an expert may not testify to a party's or non-party's intent, motive, or state of mind. *Ambassador*, 576 F. Supp. 3d at 261 (precluding expert from opining on what the SEC thought or why).

Dr. Williams' various assumptions about [redacted]

[redacted]

Ex. 2 at 34:16-24. Similarly, when merely asked about [redacted]

[redacted]

[13] "When an expert opinion is not supported by sufficient facts to validate it in the eyes of the law, or when indisputable record facts contradict or otherwise render the opinion unreasonable, it cannot support a jury's verdict." *Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 242 (1993) (disregarding unsupported facts put forth by expert at summary judgment stage).

[redacted]

Id. at 36:14 – 37:8 (emphasis added). Following up on his reference to [redacted]

[redacted]

[redacted]

Ex. 2 at 42:15 – 43:3.

But ultimately, Dr. Williams begrudgingly admitted the non-controversial reality that [redacted]

Ex. 2 at 47:7-18; *see also id.* 34:9-15 ([redacted]

[redacted]

Simply put, Dr. Williams was not at [redacted]. His opinions about what the [redacted] are nothing more than conjecture. These unreliable and unhelpful opinions should be precluded. *See, e.g.*, *Wolfe v. McNeil–PPC, Inc.*, 881 F.Supp.2d 650, 662 (E.D. Pa. 2012) (experts "will not be permitted to testify at trial with respect to the state of mind of defendants or the FDA"); *id.* at 661 ("The Court rules that expert testimony regarding the state of mind of defendants and the FDA, and expert testimony that constitutes a legal opinion, is inadmissible.").

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IV. CONCLUSION

For the foregoing reasons, Dr. Williams should be precluded from offering any opinions [redacted]

Respectfully,

ON BEHALF OF PLAINTIFFS

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on March 13, 2023, a true and correct redacted copy of the foregoing was filed and served via the court's CM/ECF system, and an unredacted version was served on the court and the Defense Executive Committee via email.

/s/ David J. Stanoch
David J. Stanoch